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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,833	12/17/2001	David John Heal	2475/002628	1200

26474 7590 11/13/2002

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[REDACTED] EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/009,833	Applicant(s) David John Heal
Examiner Ray Henley	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Oct 15, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

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CLAIMS 1-8 ARE PRESENTED FOR EXAMINATION

Applicant's Amendment filed October 15, 2002 has been received and entered into the application. Accordingly, claims 4-7 have been amended. In view thereof, the rejection of claims 4-6 under 35 USC § 112, second paragraph and of claim 7 under 35 USC § 101, as set forth in the previous Office action dated April 10, 2002 are withdrawn.

Claim Objection

Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. These claims depend from claim 1 which defines a method yet they do not contain any further limitations as to the practice of such method. Proper claims that depend from a method would read, in part, "The method of claim 1, wherein...".

Applicant is required to either cancel the claims or amend the claims to place them in proper dependent form.

Claim Rejection - 35 USC § 103

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttler (Exp. Opin. Invest. Drugs (1996), 5(12):1583-1587) and Wilding (BMJ Volume 315, 18 October 1997, pp 997-1000).

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Buttle and Wilding teach that sibutramine and orlistat are drugs which are effective for the treatment of obesity. See Buttle at page 1584, column 2, last paragraph - page 1586, column 2, last line before the heading "Concerns Over Abuse Potential" and Wilding at page 999, column 9, the entire section under the heading "Future drug targets".

The differences between the above and applicant's claimed subject matter lie in that the references fail to highlight:

- (1) the treatment of co-morbid conditions associated with obesity; and
- (2) a specific composition or method comprising both sibutramine and orlistat; and
- (3) the manufacture of a composition containing both sibutramine and orlistat.

However, to the skilled artisan, applicant's claimed subject matter would have been obvious because:

(1) the references teach the treatment of obesity in general and as such, it is believed that the skilled artisan would have readily recognized that pathophysiological sequela of obesity would also be effectively treated;

(2) Wilding at page 1000, column 1, lines 8-11 teach "[t]here are many possible new therapeutic targets, and combinations of drugs with different modes of action may be required, as is currently the case with hypertension". Insofar as sibutramine and orlistat possess differing modes of action, it is believed that a combination of the two drugs is thus reasonably suggested.

Also, it has been held that it is considered prima facie obvious to have combined two or more ingredients each of which was known to be useful for the same purpose in order to form a

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third composition that is useful for the very same purpose. The idea for combining them flows logically from their have been used separately. See In re Kerkhoven 205 U.S.P.Q. 1069 (CCPA 1980) and the cases cited therein. The skilled artisan would have been motivated to combine such ingredients in order to achieve at least additive results and to provide the individual being treated with the most convenient, effective therapy possible; and

(3) the mere mixing of ingredients to form a composition is well known in the art and would have been well within the purview of the skilled artisan to do so in seeking to provide a patient with a convenient means for taking multiple medications simultaneously.

Applicant's arguments at pages 4-5 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicant's have pointed to 5 alleged benefits to the present invention that is not taught or suggested in the prior art, e.g., synergistic results. However, the Examiner finds that it has not been demonstrated on the record, by means of appropriate experimental results, that applicant's combination of ingredients produces any results that would not have been expected from the teaching of the prior art. The mere allegations by applicant are not sufficient to establish non-obviousness.

Accordingly, the claims are deemed to be properly rejected and none of the claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1600

Henley; rjh
November 8, 2002